

|  |  |   |                                    |
|--|--|---|------------------------------------|
| Form PTO-1390  |  | U.S. DEPARTMENT OF COMMERCE<br>PATENT AND TRADEMARK OFFICE    | ATTORNEY'S DOCKET NUMBER<br>P30320 |
| TRANSMITTAL LETTER TO THE UNITED STATES<br>DESIGNATED/ELECTED OFFICE (DO/EO/US)<br>CONCERNING A FILING UNDER 35 U.S.C. 371   |  | CONFIRMATION NO. 4690   |                                    |
|  |  | U.S. APPLICATION NO. (If known, see 37 CFR 1.5)<br>10/586,454 |                                    |
| INTERNATIONAL APPLICATION NO.<br>PCT/JP2005/000979   | INTERNATIONAL FILING DATE<br>26 January 2005 | PRIORITY DATE CLAIMED<br>26 January 2004                      |                                    |
| TITLE OF INVENTION<br>MEDICAMENT FOR THERAPEUTIC TREATMENT OF PAIN   |  |   |                                    |
| APPLICANT(S) FOR DO/EO/US<br>Kozo NINOMIYA and Shuzo NINOMIYA  |  |   |                                    |
| Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information.  |  |   |                                    |
| <p>1. <input type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.</p> <p>2. <input checked="" type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.</p> <p>3. <input type="checkbox"/> This is an express request to promptly begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (23) indicated below.</p> <p>4. <input type="checkbox"/> The US has been elected (PCT Article 31).</p> <p>5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2))</p> <p>a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).</p> <p>b. <input type="checkbox"/> has been communicated by the International Bureau.</p> <p>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</p> <p>6. <input checked="" type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371 (c)(2)).</p> <p>a. <input checked="" type="checkbox"/> is attached hereto.</p> <p>b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154 (d) (4).</p> <p>7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))</p> <p>a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).</p> <p>b. <input type="checkbox"/> have been communicated by the International Bureau.</p> <p>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</p> <p>d. <input type="checkbox"/> have not been made and will not be made.</p> <p>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</p> <p>9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). <b>"EXECUTED"</b></p> <p>10. <input type="checkbox"/> An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</p> |  |   |                                    |
| <b>Items 11 to 22 below concern other document(s) or information included:</b>   |  |   |                                    |
| 11. Assignee:  |  |   |                                    |
| 12. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.   |  |   |                                    |
| 13. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.   |  |   |                                    |
| 14. <input checked="" type="checkbox"/> A FIRST preliminary amendment.<br><input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment.   |  |   |                                    |
| 15. <input type="checkbox"/> An Application Data Sheet under 37 C.F.R. 1.76.   |  |   |                                    |
| 16. <input type="checkbox"/> A substitute specification.   |  |   |                                    |
| 17. <input type="checkbox"/> A power of attorney and/or change of address letter.  |  |   |                                    |
| 18. <input type="checkbox"/> Figure of Drawing to be published:  |  |   |                                    |
| 19. <input checked="" type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821-1.825.  |  |   |                                    |
| 20. <input type="checkbox"/> A second copy of the published international application under 35 U.S.C. 154 (d) (4).   |  |   |                                    |
| 21. <input type="checkbox"/> A second copy of the English language translation of the international of the international application under 35 U.S.C. 154 (d) (4).  |  |   |                                    |
| 22. <input checked="" type="checkbox"/> Other items or information:<br>Cover Letter<br>Statement to Support Filing and Submission in Accordance with 37 C.F.R. § 1.821-1.825<br>Paper copy of the sequence listing (2 pages)<br>PCT/DO/EO/905  |  |   |                                    |

P30320.P05

|  |              |   |            |                               |              |
|--|--------------|---|------------|-------------------------------|--------------|
| U.S. APPLICATION NO. (If known, see 37 CFR 1.5)  |              | INTERNATIONAL APPLICATION NO.   |            | ATTORNEY'S DOCKET NUMBER      |              |
| 10/586,454   |              | PCT/JP2005/000979   |            | P30320                        |              |
| 23 <input type="checkbox"/> The following fees are submitted:  |              |   |            | CALCULATIONS                  | PTO USE ONLY |
| Basic national fee.....300.00  |              |   |            | \$ 0.00                       |              |
| 24 <input type="checkbox"/> Examination Fee  |              |   |            | \$ 0.00                       |              |
| If International preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33 (1)-(4).....0.00   |              |   |            |                               |              |
| All other situations.....200.00  |              |   |            |                               |              |
| 25 <input type="checkbox"/> Search fee   |              |   |            | \$ 0.00                       |              |
| Search fee (37 CFR 1.445(a) (2)) has been paid on the international application to the USPTO as an International Searching Authority.....0.00  |              |   |            |                               |              |
| International Search Report prepared and provided to the Office.....400.00   |              |   |            |                               |              |
| All other situations.....500.00  |              |   |            |                               |              |
| TOTAL 23, 24 and 25 =  |              |   |            | \$ 0.00                       |              |
| <input type="checkbox"/> Additional Fee for Specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in electronic medium). The fee is \$250.00 for each additional 50 sheets of paper or fraction thereof. |              |   |            |                               |              |
| Total Sheets   | Extra Sheets | Number of each additional 50 or fraction thereof (round up to a whole number) | RATE       |                               |              |
| -100=  | /50 =        |   | x \$250.00 | \$ 0.00                       |              |
| Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(h)).   |              |   |            | \$130.00                      |              |
| Claims   | Number Filed | Number Extra  | Rate       |                               |              |
| Total Claims   | 7 - 20 =     | 0   | x \$50.00  | \$ 0.00                       |              |
| Independent Claims   | 2 - 3 =      | 0   | x \$200.00 | \$ 0.00                       |              |
| Multiple Dependent Claim(s) (if applicable)  |              |   |            | + \$360.00                    | \$ 0.00      |
| TOTAL OF ABOVE CALCULATIONS =  |              |   |            | \$130.00                      |              |
| <input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.  |              |   |            | \$ 65.00                      |              |
| SUBTOTAL =   |              |   |            | \$ 65.00                      |              |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492 (i)).   |              |   |            | \$130.00                      |              |
| Extension of Time fee in the amount of \$  |              |   |            | \$ 0.00                       |              |
| TOTAL NATIONAL FEE =   |              |   |            | \$195.00                      |              |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property   |              |   |            | \$ 0.00                       |              |
| TOTAL FEES ENCLOSED =  |              |   |            | \$195.00                      |              |
|  |              |   |            | Amount to be refunded         | \$           |
|  |              |   |            | Charged                       | \$           |
| a. <input checked="" type="checkbox"/> A check in the amount of \$195.00 to cover the above fees is included.  |              |   |            |                               |              |
| b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees.  |              |   |            |                               |              |
| c. <input checked="" type="checkbox"/> The U.S. Patent and Trademark Office is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 19-0089.  |              |   |            |                               |              |
| d. <input type="checkbox"/> Fees are to be charged to a credit card. <b>WARNING:</b> Information on this form may become public.   |              |   |            |                               |              |
| Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.  |              |   |            |                               |              |
| <b>NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.</b>   |              |   |            |                               |              |
| SEND ALL CORRESPONDENCE TO CUSTOMER NO. 07055<br>AT THE PRESENT ADDRESS OF:  |              |   |            | SIGNATURE                     |              |
| Bruce H. Bernstein<br>GREENBLUM & BERNSTEIN, P.L.C.<br>1950 Roland Clark Place<br>Reston, VA 20191<br>(703) 716-1191   |              |   |            | Bruce H. Bernstein<br>NAME    |              |
| 07/11/2007 GFREY1 00000132 10586454  |              |   |            | 42,920<br>REGISTRATION NUMBER |              |

01 FC:2617  
02 FC:161865.00 OP  
130.00 OP

(P30320 00222598.DOC)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Kozo NINOMIYA et al.

**Mail Stop PCT  
Confirmation No. 4690**

Appl. No. : 10/586,454)  
(National Stage of PCT/JP2005/000979)

I. A. Filed : January 26, 2005

For : MEDICAMENT FOR THERAPEUTIC TREATMENT OF PAIN

**COVER LETTER**

**Mail Stop PCT**

Commissioner for Patents  
U.S. Patent and Trademark Office  
Customer Service Window, Mail Stop PCT  
Randolph Building  
401 Dulany Street  
Alexandria, VA 22314

Sir:

In order to comply with the requirements (copy enclosed) for the submission of an executed Declaration and English translation of the International Application set forth in the Notification mailed May 10, 2007 which sets a two-month period of response until July 10, 2007, Applicants hereby submit:

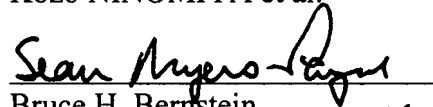
- Transmittal Letter to the United States Designated/Elected Office Concerning a Filing Under 35 U.S.C. 371;
- an executed Declaration and Power of Attorney;
- a Preliminary Amendment;
- a Verified English Language Translation of the application as filed (16 pages with abstract, 1 sheet of paper copy of the sequence listing and 8 sheets of drawings);

- Statement to Support Filing and Submission in Accordance with 37 C.F.R. § 1.821-1.825 with attached computer readable copy of the sequence listing and paper copy of the same
- a check in the amount of \$195.00 of which \$130.00 is payment for the verified English language translation of the application as filed and \$65.00 is to cover the surcharge for late filing of the Declaration.

The U.S. Patent and Trademark Office is hereby authorized to charge any additional fees or credit any overpayment to Deposit Account No. 19-0089.

Should the Examiner have any questions, he is invited to contact the undersigned at the below-listed number.

Respectfully submitted,  
Kozo NINOMIYA et al.



Bruce H. Bernstein  
Reg. No. 29,027

42,920

July 10, 2007  
GREENBLUM & BERNSTEIN, P.L.C.  
1950 Roland Clarke Place  
Reston, VA 20191  
(703) 716-1191



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address: COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450  
 www.uspto.gov

| U.S. APPLICATION NUMBER NO. | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
|-----------------------------|-----------------------|------------------|
| 10/586,454                  | Kozo Ninomiya         | P30320           |

INTERNATIONAL APPLICATION NO.

PCT/JP05/00979

I.A. FILING DATE

01/26/2005

PRIORITY DATE

01/26/2004

7055

GREENBLUM & BERNSTEIN, P.L.C.  
 1950 ROLAND CLARKE PLACE  
 RESTON, VA 20191

CONFIRMATION NO. 4690

371 FORMALITIES LETTER



\*OC000000023776518\*

Date Mailed: 05/10/2007

### NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Indication of Small Entity Status
- Copy of the International Application filed on 07/18/2006
- Copy of the International Search Report filed on 07/18/2006
- Oath or Declaration filed on 07/18/2006
- Request for Immediate Examination filed on 07/18/2006
- U.S. Basic National Fees filed on 07/18/2006
- Priority Documents filed on 07/18/2006
- Specification filed on 07/18/2006
- Claims filed on 07/18/2006
- Abstracts filed on 07/18/2006
- Drawings filed on 07/18/2006

**RECEIVED**  
**MAY 11 2007**  
**GREENBLUM & BERNSTEIN PLC**

The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Translation of the application into English. Note a processing fee will be required if submitted later than 30 months from the priority date.
- Processing fee of \$130 for providing the translation of the application and/or the Annexes later than 30 months from the priority date (37 CFR 1.492(i)).
- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date. The current oath or declaration does

not comply with 37 CFR 1.497(a) and (b) in that it:

- is not executed in accordance with either 37 CFR 1.66 or 37 CFR 1.68.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.492(h) of \$65 for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this letter.

#### SUMMARY OF FEES DUE:

Total additional fees required for this application is **\$195** for a Small Entity:

- **\$65** Surcharge.
- **\$130** for English translation surcharge required.

**ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.

<https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html>

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at <http://www.uspto.gov/ebc>.

**If you are not using EFS-Web to submit your reply, you must include a copy of this notice.**

TAMALA D HOLLAND

Telephone: (703) 308-9140 EXT 209

#### PART 1 - ATTORNEY/APPLICANT COPY

| U.S. APPLICATION NUMBER NO. | INTERNATIONAL APPLICATION NO. | ATTY. DOCKET NO. |
|-----------------------------|-------------------------------|------------------|
| 10/586,454                  | PCT/JP05/00979                | P30320           |